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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,822

Applicant(s)

HORIBA ET AL.

Examiner

SHEFALI D. PATEL

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgments

1. In the reply, filed on October 27, 2008, Applicant amended claims 6 and 8.
2. Applicant added new claims 11-18.
3. In the non-final rejection of March 18, 2008, Examiner objected to the abstract for exceeding 150 words. Applicant amended the abstract to be 150 words. Objection is withdrawn.
4. Examiner objected to the title "Catheter" for not being descriptive of the invention. Applicant amended the title to be "Catheter capable of grasping treatment region and performing injection". Objection is withdrawn.
5. Examiner objected to claim 6 for a minor informality. Applicant amended claim 6. Objection is withdrawn.
6. Currently, claims 6-18 are under examination.

Response to Arguments

7. Applicant's arguments with respect to claims 6-10 have been considered but are moot in view of the new ground(s) of rejection, based on the insertion of subject matter not previously presented in the claims into independent claim 6.

Claim Objections

8. Claims 9, 10, 16, and 18 are objected to because of the following informalities:

In regards claim 9, the preamble recites "The catheter as set forth **in any of claim 6 to 3**" and Applicant indicates that claim 9 is in the state as previously presented. However, in the previous presentation of claim 9 (Claims - 02/05/2008), the preamble recited "The catheter as set forth **in claim 6**". Therefore, it appears that an inadvertent error has been made to claim 9, and the preamble of claim 9 should be corrected as "The catheter as set forth **in claim 6**" as previously presented.

In regards claim 10, the preamble recites "The catheter as set forth **in any of claim 6 to 4**" and Applicant indicates that claim 10 is in the state as previously presented. However, in the previous presentation of claim 10 (Claims - 02/05/2008), the preamble recited "The catheter as set forth **in claim 6**". Therefore, it appears that an inadvertent error has been made to claim 10, and the preamble of claim 10 should be corrected as "The catheter as set forth **in claim 6**" as previously presented.

In regards to claim 16, the term "**a** needle" should be corrected as "**the injection** needle" since "an injection needle" was previously introduced in claim 11.

In regards to claim 18, the term "**the linking mechanism**" should be corrected as "**the linkage**", since the component was introduced as "a linkage" in prior claim 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 6, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Exconde et al (US 5,496,310), and further in view of Kratsch et al (US 5,478,350).

In regards to claim 6, Exconde et al teaches a catheter (Figures 1-3, instrument [10]) comprising:

- a. an outer tube (guide tube [40]) sized to be inserted into a blood vessel
- b. a first inner tube (shaft [22]) located within the outer tube [40] and containing a forceps mechanism (forceps [20])
- c. a second inner tube (guide sleeve [68]) also located within the outer tube [40] containing an injection mechanism (catheter [14])
- d. the forceps mechanism [20] having a first handling portion (actuator [32]) at the proximate end and a grasping portion (jaws [30]) at the distal end, the grasping portion being configured to open and close in conjunction with manipulation at the first handling portion, and being capable of holding the target region (column 8, lines 22-36)
- e. the injection mechanism [14] having a second handling portion at the proximate end, and an injection needle at the distal end, the injection needle being configured to be moved forward up to a position to be protruded from the distal end, and to be moved back up to a position to be stored inside of the distal end, the injection mechanism being capable of puncturing the target region with the injection needle and injecting injectant into the target region (Figure 1) (column 10, lines 15-23)(column 12, lines 55-58)

Exconde et al does not teach an operating linkage of the forceps mechanism [20] that is constrained within the first inner tube [22] in a closed position. Kratsch et al teaches a forceps

mechanism (Figures 15-17), wherein an operating linkage (hook [116] with curved surface [106]) of a forceps mechanism (end effectors [58][59]) is constrained within a tube (sleeve [64]) in a closed position (Figure 16). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the catheter of Exconde et al, with an operating linkage that is constrained within the first inner tube in a closed position, as taught by Kratsch et al, as the operating linkage will determine the rate at which the grasping portion closes and the rate of change in the rate at which the grasping portion closes. By proper arrangement of the operating linkage within the inner tube, the grasping portion can be arranged with constant linear movement of the handling portion to accelerate, decelerate, or vary speeds in the closing motion (column 8, lines 62-67 to column 9, lines 1-16).

In regards to claim 8, in a modified catheter of Exconde et al and Kratsch et al, Exconde et al teaches that the forceps mechanism [20] comprises a lock device that prevents the grasping portion [30] opening and closing (column 8, lines 36-39).

In regards to claim 11, Exconde et al teaches a catheter (Figures 1-3, instrument [10]) comprising:

- a. an outer tube (guide tube [40]), being sized to be inserted into a blood vessel
- b. a first inner tube (shaft [22]), located within the outer tube [40] and containing a forceps mechanism (forceps [20]) having a first handling portion (actuator [32]) at a proximate end and a grasping portion (jaws [30]) at a distal end (column 8, lines 22-36)
- c. a second inner tube (guide sleeve [68]), located within the outer tube [40] and containing an injection mechanism (catheter [14]) having a second handling portion at the

proximate end, and an injection needle at the distal end, the injection needle being configured to extend to a position to protrude from the distal end, and to retract to a position to be stored inside of the distal end, the injection mechanism being capable of puncturing the target region with the injection needle and injecting injectant into the target region (Figure 1) (column 10, lines 15-23)(column 12, lines 55-58)

Exconde et al does not teach an operating linkage of the forceps mechanism [20] that is constrained within the first inner tube [22] in a closed position. Kratsch et al teaches a forceps mechanism (Figures 15-17), wherein an operating linkage (hook [116] with curved surface [106]) of a forceps mechanism (end effectors [58][59]) is constrained within a tube (sleeve [64]) in a closed position (Figure 16). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the catheter of Exconde et al, with an operating linkage that is constrained within the first inner tube in a closed position, as taught by Kratsch et al, as the operating linkage will determine the rate at which the grasping portion closes and the rate of change in the rate at which the grasping portion closes. By proper arrangement of the operating linkage within the inner tube, the grasping portion can be arranged with constant linear movement of the handling portion to accelerate, decelerate, or vary speeds in the closing motion (column 8, lines 62-67 to column 9, lines 1-16).

11. Claims 7, 12-15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Exconde et al and Kratsch et al, as applied to claims 6 and 11 above, and further in view of Clement et al (US 5,350,384).

In regards to claims 7 and 12-15, in a modified catheter of Exconde et al and Kratsch et al, neither Exconde et al nor Kratsch et al teach a spring that biases the grasping portion of the forceps mechanism toward a direction to close the grasping portion. Exconde et al only teaches that the forceps mechanism [20] comprises a lock device that prevents the grasping portion [30] opening and closing (column 8, lines 36-39). Clement et al teaches a forceps mechanism (Figures 1-6B) wherein a spring (compression spring [44]) biases a grasping portion (jaws [32]) of the forceps mechanism toward a direction to close the grasping portion (Figures 5-6B). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the modified catheter of Exconde et al and Kratsch et al, with a spring, as taught by Clement et al, as the spring will urge the grasping portion to a normally closed position while X-rays are taken of the target region (column 3, lines 1-3)(column 4, lines 2-10).

In regards to claim 18, in a modified catheter of Exconde et al and Kratsch et al, neither Exconde et al nor Kratsch et al teaches that the linking mechanism comprises a four-bar mechanism. Clement et al teaches a forceps mechanism (Figures 1-6B) wherein a linking mechanism comprises a four-bar mechanism (jaws [32] and spreader links [38]) (Figures 6A-6B). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the linking mechanism, of the forceps mechanism of the modified catheter of Exconde et al and Kratsch et al, with a four-bar mechanism, as taught by Clement et al, as the four-bar mechanism will allow the grasping portion to laterally spread in the open position for clamping around a patient's body portion and laterally compress in the closed position for storage (column 3, lines 59-68).

12. Claims 9, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Exconde et al and Kratsch et al, as applied to claims 6 and 11 above, and further in view of Haughton et al (US 5,376,075).

In regards to claims 9, 16, and 17, in a modified catheter of Exconde et al and Kratsch et al, Exconde et al does not teach a spring that biases the injection needle of the injection mechanism [14] toward a direction to move back the injection needle. Haughton et al teaches an injection mechanism (Figures 6-10), wherein a spring (spring [148]) biases an injection needle (trocar [130]) of the injection mechanism toward a direction to move back the injection needle (Figures 8-9). Haughton et al also teaches that the injection mechanism further comprises a piston (stud [146]) and a cylinder (hub [142]) for overcoming the bias of the spring [148] with a locking device (stud [146] in slots [150][152]) for maintaining the needle in the extended position. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the injection mechanism, of the modified catheter of Exconde et al and Kratsch et al, with a spring, piston, cylinder, and locking device, as taught by Haughton et al, as the spring will urge the injection needle inwardly away from its extended position in order to enclose the sharpened end of the injection needle after use (Abstract)(column 6, lines 39-59).

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Exconde et al and Kratsch et al, as applied to claim 6 above, and further in view of Yoon (US 5,921,993).

In regards to claim 10, in a modified catheter of Exconde et al and Kratsch et al, Exconde et al does not teach that the injection mechanism comprises a lock device that forbids the

injection needle moving back. Yoon teaches an injection mechanism (Figures 29-31) wherein a lock device (locking mechanism [447']) forbids an injection needle (needle [404]) from moving back (column 25, lines 30-36). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the injection mechanism, of the modified catheter of Exconde et al and Kratsch et al, with a lock device, as taught by Yoon, as the lock device will lock the second handling portion at a desired distance of needle protrusion from the second inner tube and the catheter (column 25, lines 30-36).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Evard et al (US 5,425,705), Komiya (US 4,043,323), Oz (US 2006/0235368), Ishikawa et al (US 2003/0216749), Ouchi (US 5,904,647), Hasson (US 5,250,056), Levin et al (US 2003/0130693), Ouchi (US 6,013,095), Slater (US 5,417,709), Bilweis (US 5,242,427), Terayama (US 4,222,380).

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
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/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767